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Attorneys for Defendant Merck & Co., Inc.

UNITED STATES DISTRICT COURT SOUTHERN DISTRICT OF NEW YORK

IN RE:

Fosamax Products Liability Litigation 1:06-md-1789 (JFK)

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ANSWER AND AFFIRMATIVE This Document Relates to:

Marilyn Eisenstein **DEFENSES OF MERCK**

v. Merck & Co., Inc. & CO., INC.;

DEMAND FOR JURY TRIAL

Case No: 1:08-cv-01895-JFK

Defendant, Merck & Co., Inc. ("Merck"), by and through its undersigned attorneys, hereby answers the Complaint. Merck denies all allegations set forth in the Complaint except to the extent such allegations are specifically admitted below:

I. JURISDICTION AND VENUE

The allegations of the first sentence of Paragraph 1 are conclusions of law 1. to which no response is required. To the extent that a response is required, Merck denies each and every allegation of the first sentence of Paragraph 1. As to the allegations of the second sentence of Paragraph 1, Merck is without knowledge or information sufficient to form a belief as to these allegations, except that Merck admits that it is a corporation organized under the laws of the State of New Jersey with its principal place of business in New Jersey. Merck is without knowledge as to the allegations in the third sentence of

Paragraph 1, but for jurisdictional purposes only, admits that the Plaintiff seeks in excess of \$75,000.

2. The allegations of Paragraph 2 are conclusions of law to which no response is required. To the extent a response is required, Merck denies the allegations of Paragraph 2, except that Merck admits that pursuant to Section 4 of Case Management Order No. 3 entered by Judge John F. Keenan on November 1, 2006, this action may be filed directly in the Southern District of New York. Merck reserves all rights under Section 4 of Case Management Order No. 3 and respectfully refers the Court to the relevant Case Management Order.

II. PARTIES

- 3. Merck lacks knowledge or information sufficient to form a belief as to the truth or falsity of the allegations of Paragraph 3.
- 4. Merck admits that it is a corporation organized under the laws of the State of New Jersey with its principal place of business in New Jersey. Except as expressly admitted herein, Merck denies the remaining allegations of Paragraph 4.
- Merck admits that it is registered to do business in the State of New Jersey.
- 6. Merck is without knowledge as to what is meant by the phrase "regularly transacted," so the allegations in Paragraph 6 are denied.
- 7. Merck denies each and every allegation of Paragraph 7, except that it admits that Merck manufactured, marketed, and distributed the prescription medicine FOSAMAX® for prescription in accordance with its approved prescribing information. Merck denies any allegations in Paragraph 7 inconsistent with that prescribing

information and respectfully refers the Court to the Physicians' Desk Reference ("PDR") for FOSAMAX® for its actual language and full text.

- 8. Merck admits only that it distributed FOSAMAX® for prescription in accordance with its approved prescribing information and denies any allegations in Paragraph 8 inconsistent with that prescribing information. Merck respectfully refers the Court to the PDR for FOSAMAX® for its actual language and full text. Except as expressly admitted herein, Merck denies the remaining allegations of Paragraph 8.
- 9. Merck is without knowledge as to what is meant by the phrase "substantial revenue," so the allegations in Paragraph 9 are denied.
- 10. Merck is without knowledge as to what is meant by "consequences," so the allegations in Paragraph 10 are denied.

III. SUMMARY OF THE CASE

- 11. Merck denies each and every allegation of Paragraph 11, except that it admits that Merck manufactured, marketed, and distributed the prescription medicine FOSAMAX® for prescription in accordance with its approved prescribing information.
 - 12. Merck denies each and every allegation of Paragraph 12.
 - 13. Merck denies each and every allegation of Paragraph 13.
 - 14. Merck denies each and every allegation of Paragraph 14.
 - 15. Merck denies each and every allegation of Paragraph 15.

IV. FACTUAL BACKGROUND

16. Merck denies each and every allegation of Paragraph 16, except that it admits that Merck manufactured, marketed, and distributed the prescription medicine FOSAMAX® for prescription in accordance with its approved prescribing information.

- 17. Merck denies each and every allegation of Paragraph 17, except that Merck admits that it sought and, in 1995, first obtained FDA approval to manufacture and market FOSAMAX® 10 mg and FOSAMAX® 40 mg tablets, a prescription medication approved by the FDA for prescription in accordance with its approved prescribing information. Merck denies any allegations in Paragraph 17 inconsistent with that prescribing information.
- 18. Merck admits only that FOSAMAX® is a prescription medication approved by the FDA for prescription in accordance with its approved prescribing information and denies any allegations in Paragraph 18 inconsistent with that prescribing information. Merck also refers the Court to the prescribing information for Aredia and Zometa, and denies any allegations in Paragraph 18 with respect to Aredia and Zometa inconsistent with that prescribing information.
- 19. Merck admits only that some bisphosphonates contain nitrogen and some do not and that FOSAMAX® is a prescription medication approved by the FDA for prescription in accordance with its approved prescribing information. Merck denies any allegations in Paragraph 19 inconsistent with that prescribing information. Merck respectfully refers the Court to the PDR for FOSAMAX® for its actual language and full text. Merck also refers the Court to the prescribing information for Aredia, Boniva, Actonel, Didronel, Bonefos, Loron, and Skelid, and denies any allegations in Paragraph 19 with respect to Aredia, Boniva, Actonel, Didronel, Bonefos, Loron, and Skelid inconsistent with that prescribing information. Merck denies the remaining allegations of Paragraph 19.
 - 20. Merck denies each and every allegation of Paragraph 20.

- 21. Merck denies each and every allegation of Paragraph 21.
- 22. Merck denies each and every allegation of Paragraph 22.
- 23. Merck lacks knowledge or information sufficient to form a belief as to the truth or falsity of the allegations of Paragraph 23.
 - 24. Merck denies each and every allegation of Paragraph 24.
 - 25. Merck denies each and every allegation of Paragraph 25.
 - 26. Merck denies each and every allegation of Paragraph 26.
 - 27. Merck denies each and every allegation of Paragraph 27.
- 28. Merck denies each and every allegation of Paragraph 28, except that Merck admits that the FDA drafted an "ODS Postmarketing Safety Review," but respectfully refers the Court to said document for its actual language and full text.
 - 29. Merck denies each and every allegation of Paragraph 29.
 - 30. Merck denies each and every allegation of Paragraph 30.
 - 31. Merck denies each and every allegation of Paragraph 31.
- 32. Merck denies each and every allegation of Paragraph 32, except that Merck admits that Fosamax product sales in 2007 amounted to approximately \$3.05 billion.
- 33. Merck is without knowledge as to whether Plaintiff used FOSAMAX®.

 Merck denies the remaining allegations in Paragraph 33.
 - 34. Merck denies each and every allegation of Paragraph 34.
- 35. Merck is without knowledge as to whether Plaintiff was prescribed FOSAMAX®. Merck denies the remaining allegations in Paragraph 35.
 - 36. Merck denies each and every allegation of Paragraph 36.

- 37. Merck lacks knowledge or information sufficient to form a belief as to the truth or falsity of the allegations of Paragraph 37.
- 38. Merck lacks knowledge or information sufficient to form a belief as to the truth or falsity of the allegations of Paragraph 38.
 - 39. Merck denies each and every allegation of Paragraph 39.
 - 40. Merck denies each and every allegation of Paragraph 40.
- 41. Merck lacks knowledge or information sufficient to form a belief as to the truth or falsity of the allegations of Paragraph 41.
 - 42. Merck denies each and every allegation of Paragraph 42.
 - 43. Merck denies each and every allegation of Paragraph 43.
 - 44. Merck denies each and every allegation of Paragraph 44.

V. COUNTS

COUNT I: NEGLIGENCE

- 45. Merck repleads its answers to Paragraphs 1 through and including 44, and by this reference hereby incorporates the same herein in this paragraph, and makes the same a part hereof as though fully set forth *verbatim*.
- 46. The allegations in Paragraph 46 are conclusions of law to which no response is required; to the extent that a response is deemed necessary, the allegations are denied and Merck respectfully refers the Court to the relevant legal standard, including any conflict of law rules.
- 47. Merck denies each and every allegation of Paragraph 47, including each and every allegation contained in subparts (a) through (f).
 - 48. Merck denies each and every allegation of Paragraph 48.

49. Merck denies each and every allegation of Paragraph 49.

COUNT II: STRICT LIABILITY

- 50. Merck repleads its answers to Paragraphs 1 through and including 49, and by this reference hereby incorporates the same herein in this paragraph, and makes the same a part hereof as though fully set forth *verbatim*.
- 51. Merck denies each and every allegation of Paragraph 51, except that it admits that Merck manufactured, marketed and distributed the prescription medicine FOSAMAX® for prescription in accordance with its approved prescribing information.
- 52. Merck denies each and every allegation of Paragraph 52, except that it admits that Merck manufactured, marketed and distributed the prescription medicine FOSAMAX® for prescription in accordance with its approved prescribing information and states that it is without knowledge as to the condition of the FOSAMAX® Plaintiff alleges she consumed.
- 53. Merck lacks knowledge or information sufficient to form a belief as to the truth or falsity of the allegations of Paragraph 53.
 - 54. Merck denies each and every allegation of Paragraph 54.
 - 55. Merck denies each and every allegation of Paragraph 55.
 - 56. Merck denies each and every allegation of Paragraph 56.
 - 57. Merck denies each and every allegation of Paragraph 57.
 - 58. Merck denies each and every allegation of Paragraph 58.
 - 59. Merck denies each and every allegation of Paragraph 59.
 - 60. Merck denies each and every allegation of Paragraph 60.
 - 61. Merck denies each and every allegation of Paragraph 61.

COUNT III: BREACH OF EXPRESS WARRANTY

- 62. Merck repleads its answers to Paragraphs 1 through and including 61, and by this reference hereby incorporates the same herein in this paragraph, and makes the same a part hereof as though fully set forth *verbatim*.
- 63. Merck denies each and every allegation of Paragraph 63, and respectfully refers the Court to the FDA-approved prescribing information for any and all representations contained therein. Merck further avers that FOSAMAX® is a prescription medication approved by the FDA for prescription in accordance with its approved prescribing information.
 - 64. Merck denies each and every allegation of Paragraph 64.
 - 65. Merck denies each and every allegation of Paragraph 65.
- 66. Merck lacks knowledge or information sufficient to form a belief as to the truth or falsity of the allegations of Paragraph 66.
 - 67. Merck denies each and every allegation of Paragraph 67.
 - 68. Merck denies each and every allegation of Paragraph 68.

COUNT IV: BREACH OF IMPLIED WARRANTY

- 69. Merck repleads its answers to Paragraphs 1 through and including 68, and by this reference hereby incorporates the same herein in this paragraph, and makes the same a part hereof as though fully set forth *verbatim*.
- 70. Merck denies each and every allegation of Paragraph 70, except that Merck admits that it manufactured, marketed, and distributed the prescription medicine FOSAMAX® for prescription in accordance with its approved prescribing information.

- 71. Merck denies each and every allegation of Paragraph 71, and respectfully refers the Court to the FDA-approved prescribing information for any and all representations contained therein. Merck further avers that FOSAMAX® is a prescription medication approved by the FDA for prescription in accordance with its approved prescribing information.
 - 72. Merck denies each and every allegation of Paragraph 72.
- 73. Merck lacks knowledge or information sufficient to form a belief as to the truth or falsity of the allegations of Paragraph 73.
 - 74. Merck denies each and every allegation of Paragraph 74.
- 75. Merck lacks knowledge or information sufficient to form a belief as to the truth or falsity of the allegations of Paragraph 75.
- 76. Merck lacks knowledge or information sufficient to form a belief as to the truth or falsity of the allegations of Paragraph 76.
 - 77. Merck denies each and every allegation of Paragraph 77.
 - 78. Merck denies each and every allegation of Paragraph 78.

COUNT V: FRAUDULENT MISREPRESENTATION

- 79. Merck repleads its answers to Paragraphs 1 through and including 78, and by this reference hereby incorporates the same herein in this paragraph, and makes the same a part hereof as though fully set forth *verbatim*.
- 80. Merck denies each and every allegation of Paragraph 80, including each and every allegation contained in subparts (a) and (b).
 - 81. Merck denies each and every allegation of Paragraph 81.
 - 82. Merck denies each and every allegation of Paragraph 82.

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- 83. Merck denies each and every allegation of Paragraph 83.
- 84. Merck denies each and every allegation of Paragraph 84.
- 85. Merck denies each and every allegation of Paragraph 85.
- 86. Merck denies each and every allegation of Paragraph 86.
- 87. Merck denies each and every allegation of Paragraph 87.

COUNT VI: FRAUDULENT CONCEALMENT

- 88. Merck repleads its answers to Paragraphs 1 through and including 87, and by this reference hereby incorporates the same herein in this paragraph, and makes the same a part hereof as though fully set forth *verbatim*.
- 89. Merck denies each and every allegation of Paragraph 89, including each and every allegation contained in subparts (a) and (b).
 - 90. Merck denies each and every allegation of Paragraph 90.
 - 91. Merck denies each and every allegation of Paragraph 91.
 - 92. Merck denies each and every allegation of Paragraph 92.
 - 93. Merck denies each and every allegation of Paragraph 93.
 - 94. Merck denies each and every allegation of Paragraph 94.
 - 95. Merck denies each and every allegation of Paragraph 95.

GLOBAL PRAYER FOR RELIEF

Merck denies that Plaintiff is entitled to any of the relief requested in her Global Prayer for Relief.

WHEREFORE, Merck respectfully demands judgment dismissing Plaintiff's Complaint with prejudice and awarding Merck such other and further relief that the Court may deem just and proper.

ADDITIONAL DEFENSES

Discovery and investigation may reveal that any one or more of the following additional defenses should be available to Merck in this matter. Merck, therefore, asserts said additional defenses in order to preserve the right to assert them. Upon completion of discovery, and if the facts warrant, Merck may withdraw any of these additional defenses as it may deem appropriate. Further, Merck reserves the right to amend its Answer to assert additional defenses, cross-claims, counterclaims, and other claims and defenses as discovery proceeds. Merck demands strict proof of all claims and allegations contained in Plaintiff's Complaint that Merck has not expressly admitted. Further answering and by way of additional defense, Merck states as follows:

FIRST ADDITIONAL DEFENSE

Each and every claim asserted or raised in the Complaint is barred by the applicable statute of limitations and is otherwise untimely.

SECOND ADDITIONAL DEFENSE

The Complaint fails to state a claim upon which relief can be granted.

THIRD ADDITIONAL DEFENSE

This case is more appropriately brought in a different venue.

FOURTH ADDITIONAL DEFENSE

If Plaintiff has sustained injuries or losses as alleged in the Complaint, upon information and belief, such injuries or losses were caused in whole or in part through the operation of nature or other intervening cause or causes.

FIFTH ADDITIONAL DEFENSE

Plaintiff is barred from recovering against Merck because Plaintiff's claims are preempted in accordance with the Supremacy Clause of the United States Constitution and by applicable federal law, including the Federal Food, Drug and Cosmetic Act, 21 U.S.C. 301 et seq.

SIXTH ADDITIONAL DEFENSE

To the extent that Plaintiff asserts claims based upon an alleged failure by Merck to warn Plaintiff directly of alleged dangers associated with the use of FOSAMAX®, such claims are barred under the learned intermediary doctrine because Merck has discharged its duty to warn in its warnings to prescribing physician. Plaintiff's claims are barred because Merck has discharged its duty to warn under N.J.S.A. 2A:58C-4 in its warning to prescribing physicians.

SEVENTH ADDITIONAL DEFENSE

Other persons or entities who are not parties to this suit were guilty of negligence which was the sole proximate cause of, or a contributing cause to, the damages alleged in the Complaint. Merck anticipates more specific information regarding the identity and potential liability of these non-parties will be developed during discovery. Accordingly, any damages awarded should be apportioned or reduced in accordance with the applicable law.

EIGHTH ADDITIONAL DEFENSE

The injuries and damages, if any, sustained by Plaintiff resulted in whole or in part from her own contributory or comparative negligence and any damages recovered should be reduced and/or barred in accordance with the applicable law.

NINTH ADDITIONAL DEFENSE

If Plaintiff has sustained injuries or losses as alleged in the Complaint, such injuries or losses were only sustained after Plaintiff knowingly, voluntarily, and willfully assumed the risk of any injury as the result of the consumption of, administration of, or exposure to any medicine or pharmaceutical preparation manufactured or distributed by Merck or other manufacturer.

TENTH ADDITIONAL DEFENSE

If Plaintiff has sustained injuries or losses as alleged in the Complaint, upon information and belief, such injuries and losses were caused by the actions of persons not having real or apparent authority to take said actions on behalf of Merck and over whom Merck had no control and for whom Merck may not be held accountable.

ELEVENTH ADDITIONAL DEFENSE

If Plaintiff has sustained injuries or losses as alleged in the Complaint, upon information and belief, such injuries and losses were proximately caused by Plaintiff's misuse or abuse of FOSAMAX®.

TWELFTH ADDITIONAL DEFENSE

If Plaintiff has sustained injuries or losses as alleged in the Complaint, such injuries or losses resulted from Plaintiff's pre-existing and/or unrelated medical, genetic and/or environmental conditions, diseases, or illnesses, idiosyncratic reactions, subsequent medical conditions or natural courses of conditions for which this Defendant is not responsible.

THIRTEENTH ADDITIONAL DEFENSE

Plaintiff's claims for breach of warranty are also barred for lack of timely notice of breach and/or lack of privity.

FOURTEENTH ADDITIONAL DEFENSE

Plaintiff's claims are barred in whole or in part under the applicable state law because FOSAMAX® was subject to and received pre-market approval by the FDA under 52 Stat. 1040, 21 U.S.C. § 301.

FIFTEENTH ADDITIONAL DEFENSE

Plaintiff's claims are barred in whole or in part because the product at issue was made in accordance with the state of the art at the time it was manufactured.

SIXTEENTH ADDITIONAL DEFENSE

To the extent that Plaintiff seeks punitive damages for the conduct which allegedly caused the injuries asserted in the Complaint, such an award would, if granted, violate Merck's state and federal constitutional rights.

SEVENTEENTH ADDITIONAL DEFENSE

To the extent that Plaintiff seeks punitive damages for an alleged act or omission of Merck, no act or omission was malicious, willful, wanton, reckless or grossly negligent and, therefore, any award of punitive damages is barred.

EIGHTEENTH ADDITIONAL DEFENSE

To the extent that Plaintiff seeks punitive damages, such claims are barred because FOSAMAX® and its labeling was subject to and received pre-market approval by the FDA under 52 Stat. 1040, 21 U.S.C. § 301.

NINETEENTH ADDITIONAL DEFENSE

Plaintiff's claims are barred in whole or in part under comment k to Section 402A of the Restatement (Second) of Torts.

TWENTIETH ADDITIONAL DEFENSE

Plaintiff's claims are barred in whole or in part because Merck provided legally adequate "directions or warnings" as to the use of FOSAMAX® and any other medicine or pharmaceutical preparation Plaintiff alleges to have taken within the meaning of comment j to Section 402A of the Restatement (Second) of Torts.

TWENTY-FIRST ADDITIONAL DEFENSE

Plaintiffs' claims are barred under Section 4, et seq., of the Restatement (Third) of Torts: Products Liability.

TWENTY-SECOND ADDITIONAL DEFENSE

Plaintiff's claims are barred under comment f to Section 6 of the Restatement (Third) of Torts: Products Liability.

TWENTY-THIRD ADDITIONAL DEFENSE

There is no practical or technically feasible alternative design that would have reduced the alleged risk without substantially impairing the reasonably anticipated and intended function of FOSAMAX®.

TWENTY-FOURTH ADDITIONAL DEFENSE

Plaintiff's claims are barred in whole or in part by failure to prevent or mitigate damages.

TWENTY-FIFTH ADDITIONAL DEFENSE

Plaintiff's claims are barred in whole or in part because Merck's conduct conforms with medical knowledge.

TWENTY-SIXTH ADDITIONAL DEFENSE

With respect to each and every cause of action, Plaintiff cannot state claims founded in strict liability because, among other things, comments j and k to Section 402A of the Restatement (Second) of Torts relegates Plaintiff's claims to a negligence cause of action.

TWENTY-SEVENTH ADDITIONAL DEFENSE

All activities of Merck as alleged in the Complaint were expressly authorized and/or regulated by a government agency. Therefore, Plaintiff's claims pertaining to unfair or deceptive practices are barred.

TWENTY-EIGHTH ADDITIONAL DEFENSE

With respect to each and every cause of action, Plaintiff is not entitled to recover because if the product involved was unsafe, which Merck denies, then it was unavoidably unsafe as defined in Restatement of Torts. The apparent benefits of the product exceeded any apparent risk given the scientific knowledge available when the product was marketed.

TWENTY-NINTH ADDITIONAL DEFENSE

Merck's advertisements and labeling with respect to the products which are the subject matter of this action were not false or misleading and, therefore, constitute protected commercial speech under the applicable provisions of the United States, New Jersey, and New York Constitutions.

THIRTIETH ADDITIONAL DEFENSE

The public interest in the benefit and availability of the product which is the subject matter of this action precludes liability for risks, if any, resulting from any activities undertaken by Defendant, which were unavoidable given the state of human knowledge at the time those activities were undertaken. With respect to Plaintiff's claims, if it is determined there is a risk inherent in the product which is the subject matter of this action, then such risk, if any, is outweighed by the benefit of the product.

THIRTY-FIRST ADDITIONAL DEFENSE

At all times relevant herein, any product which is the subject matter of this action manufactured and distributed by Merck in any state in the United States was manufactured and distributed in a reasonable and prudent manner based upon available medical and scientific knowledge and further was manufactured and distributed in accordance with and pursuant to all applicable regulations of the FDA.

THIRTY-SECOND ADDITIONAL DEFENSE

With respect to each and every purported cause of action, the acts of Merck were at all times done in good faith and without malice.

THIRTY-THIRD ADDITIONAL DEFENSE

To the extent there were any risks associated with the use of the product which is the subject matter of this action which Merck knew or should have known and which gave rise to a duty to warn, Merck at all times discharged such duty through appropriate and adequate warnings in accordance with federal and state law.

THIRTY-FOURTH ADDITIONAL DEFENSE

Plaintiff has not sustained an ascertainable loss of property or money.

THIRTY-FIFTH ADDITIONAL DEFENSE

Plaintiff has not suffered any actual injury or damages.

THIRTY-SIXTH ADDITIONAL DEFENSE

Plaintiff's claims are barred under the doctrine of economic loss.

THIRTY-SEVENTH ADDITIONAL DEFENSE

Merck is entitled to a set-off or reduction in any damages which may be awarded to the Plaintiff for any amounts received from collateral sources.

THIRTY-EIGHTH ADDITIONAL DEFENSE

To the extent that Plaintiff asserts claims based on Merck's adherence to and compliance with applicable state laws, regulations and rules, such claims are preempted by federal law under the Final Rule, Requirements on Content and Format of Labeling for Human Prescription Drug and Biologic Products, FDA Docket No. 2000N-1269 (January 24, 2006).

THIRTY-NINTH ADDITIONAL DEFENSE

Plaintiff's claims of fraud are not pleaded with the required particularity.

FORTIETH ADDITIONAL DEFENSE

Plaintiff's claims are barred and/or this Court should defer this matter, in whole or in part, pursuant to the doctrine of primary jurisdiction; the FDA is charged under the law with regulating prescription drugs, including FOSAMAX®, and is specifically charged with determining the content of warnings and labeling for prescription drugs.

FORTY-FIRST ADDITIONAL DEFENSE

To the extent Plaintiff's claims are based on alleged misrepresentations or omissions made to the FDA, such claims are barred pursuant to Buckman Co. v. Plaintiff's Legal Committee, 531 U.S. 341 (2001).

FORTY-SECOND ADDITIONAL DEFENSE

There is no causal relationship between Merck or its activities described in the Complaint and any injuries or damages allegedly sustained by Plaintiff.

FORTY-THIRD ADDITIONAL DEFENSE

To the extent Plaintiff has settled or will in the future settle with any person or entity with respect to the injuries asserted in the Complaint, Merck's liability, if any, should be reduced accordingly.

FORTY-FOURTH ADDITIONAL DEFENSE

To the extent Plaintiff is seeking recovery for benefits entitled to be received or actually received from any source for injuries in the Complaint, such benefits are not recoverable in this action under N.J.S.A. 2A:15-97.

FORTY-FIFTH ADDITIONAL DEFENSE

The defendant is not guilty of negligence and violated no duty owing to Plaintiff.

FORTY-SIXTH ADDITIONAL DEFENSE

Plaintiff's claims are barred, in whole or in part, because Plaintiff lacks capacity and/or standing to bring such claims.

FORTY-SEVENTH ADDITIONAL DEFENSE

The extent of any risk associated with the use of Merck's product, the existence of which is not admitted, was, at the time of the distribution of the product by Merck, unknown and could not have been known by the use of ordinary care by Merck.

FORTY-EIGHTH ADDITIONAL DEFENSE

Each and every claim asserted or raised in the Complaint is barred by the doctrine of accord and satisfaction, res judicata, payment and/or release.

FORTY-NINTH ADDITIONAL DEFENSE

Plaintiff's damages are barred or reduced by the doctrine of avoidable consequences.

FIFTIETH ADDITIONAL DEFENSE

With respect to Plaintiff's demand for punitive damages, Merck specifically incorporates by reference all standards of limitations regarding the determination and enforceability of punitive damage awards which arose in the decisions of <u>BMW of North</u> America v. Gore, 116 U.S. 1589 (1996), Cooper Industries, Inc. v. Leatherman Tool Group, Inc., 532 U.S. 424 (2001), and State Farm Mut. Auto. Ins. Co. v. Campbell, 123 S.Ct. 1513 (U.S. 2003).

FIFTY-FIRST ADDITIONAL DEFENSE

To the extent that Plaintiff attempts to seek equitable relief, Plaintiff is not entitled to such relief because Plaintiff has an adequate remedy at law.

FIFTY-SECOND ADDITIONAL DEFENSE

Plaintiff is barred from recovery and/or Plaintiff's recovery is limited pursuant to the Comparative Negligence Act, N.J.S.A. 2A:15-5.1, et seq.

FIFTY-THIRD ADDITIONAL DEFENSE

Merck denies any liability on its part, but if Merck is ultimately found liable to Plaintiff, then it shall only be liable for its equitable share of Plaintiff's recovery since any liability which would be found against it will be insufficient to impose joint liability. In the alternative, the liability, if any, of Merck is limited by and pursuant to the New Jersey Joint Tortfeasor Contribution Act, N.J.S.A. 2A:53A-1, et seq.

FIFTY-FOURTH ADDITIONAL DEFENSE

Each and every claim asserted or raised in the Complaint is barred by the doctrines of estoppel or waiver.

FIFTY-FIFTH ADDITIONAL DEFENSE

Merck asserts all defenses available to it pursuant to N.J.S.A. 2A:58C-1, et seq., otherwise known as the New Jersey Product Liability Act.

FIFTY-SIXTH ADDITIONAL DEFENSE

Plaintiff fails to state a claim upon which relief can be granted for medical monitoring or compensation for medical monitoring.

Inasmuch as the Complaint does not describe the alleged underlying claims with sufficient particularity to enable Merck to determine all of its legal, contractual and equitable rights, Merck reserves the right to amend and/or supplement the averments of its Answer to assert any and all pertinent liability defenses ascertained through further investigation and discovery.

Merck will rely on all defenses that may become available during discovery or trial.

WHEREFORE, Merck respectfully demands judgment dismissing the Complaint with prejudice and awarding Merck its reasonable costs and disbursements, including reasonable attorneys' fees, together with such and other and further relief that the Court may deem just and proper.

JURY DEMAND

Merck demands a trial by jury as to all issues so triable.

DATED: New York, New York April 28, 2008

Respectfully submitted,

HUGHES HUBBARD & REED LLP

By: /s/
Norman C. Kleinberg
Theodore V. H. Mayer
William J. Beausoleil

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Attorneys for Defendant Merck & Co., Inc.

CERTIFICATE OF SERVICE

I hereby certify that on this 28th day of April, 2008, I caused a copy of the foregoing ANSWER AND AFFIRMATIVE DEFENSES OF MERCK & CO., INC. to be served via first-class mail, postage prepaid, on the following:

LEVIN PAPANTONIO THOMAS MITCHELL ECHSNER & PROCTOR PA Meghan M. Tans Timothy M. O'Brien 316 South Baylen Street Suite 600 (32502) P.O. Box 12308 Pensacola, FL 32591

The above addresses have appeared on the prior papers in this action as the office address of the attorneys for Plaintiff.

Deponent is over the age of 18 years and not a party to this action.

I further certify under penalty of perjury that under the laws of the United States of America the foregoing is true and correct.

Executed on April 28, 2008

/s/	
Shawn McEnnis	